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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,137	08/29/2001	Christopher M. Angelucci	8932-538	6603
20583	7590	04/13/2005		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER ROBERT, EDUARDO C	
			ART UNIT 3732	PAPER NUMBER

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,137

Applicant(s)

ANGELUCCI ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 9-12, 22, 26 and 32-50 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-25, 27, 53-60 and 63-68 is/are allowed.
- 6) ☒ Claim(s) 1-8, 13, 14, 16-21, 28-31, 51, 52, 61 and 62 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/20/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

This application contains claims 9-12, 22, 26, and 32-50 drawn to an invention nonelected with traverse in Paper No. 7. **A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.**

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75 (d)(1) and M.P.E.P § 608.01 (1). Correction of the following is required: the bone engaging portions comprises a bone receiving channel that extends a substantial portion of the length of the bone engaging portion, as per claim 1, should be properly included in the specification.

Claim Objections

Claims 53-68 are objected to because of the following informalities:

In claim 53, line 1, "the spinal column" should be changed to -- a patient's spinal column --. It would be considered as such for examination purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 61, lines 1 and 2, "the intermedullary canal of the donor bone" lacks a prior antecedent.

In claim 62, lines 2 and 3, "the intermedullary canal of the donor bone" lacks a prior antecedent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 6, 7, 13, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul et al. (Reference "WO 99/38461" cited on IDS).

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Paul et al. disclose an implant comprising a body portion, e.g. 10, having a length, a width and a depth. The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface, e.g. 26 (see Figure 7), and an inner surface defining a substantially hollow portion, e.g. 11. The body portion further has first and second ends, e.g. 14 and 16, which communicate with the hollow portion 11. The first and second ends comprise bone engaging portions comprising rough surfaces that include peaks, i.e. teeth 12, and valleys, i.e. space between teeth. The valleys are considered cutouts. The rough surfaces, i.e. peaks and valleys, are adapted to engage and retain one of the cut bone segments. The perimeter of the outer surface of the implant is a geometric shape, e.g. oval, square, etc. (see Figures 7 and 9). One embodiment of the implant is oval or elliptical (see Figure 7). The implant is tubular shape, e.g. Figure 8. The implant is formed from bone allograft material.

Claims 1, 2, 5, 6, and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by McKay (Reference US Patent "6,039,762" cited on IDS).

McKay discloses an implant comprising a body portion, e.g. 15, having a length, a width and a depth. The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface and an inner surface defining a substantially hollow portion 18 (see Figure 2). The body portion further has first and second ends that communicate with the hollow portion 18. The first and second ends comprise bone engaging portions having cutouts (see Figures 2-4). The perimeter of the outer surface of the implant is a geometric shape, e.g. circle (see Figure 2). The implant is tubular shape. The cutout includes at least two angled faces. The implant further includes at least one hole, e.g. 16, in communication

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with the outer surface and the inner surface. The implant is fabricate from biocompatible metal or any other material stronger than the porous biocompatible material 11 (see col. 5, lines 46-58).

Claims 1, 2, and 16-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Yonenobu et al. (Reference "JPO2000175943" cited on IDS).

Yonenobu et al. disclose an implant comprising a body portion 10 having a length, a width and a depth (see Figure 1). The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface and an inner surface defining a substantially hollow portion 17. The body portion further has first and second ends that communicate with the hollow portion 18 (see Figure 1B). The first and second ends comprise bone engaging portions 13, 14 having cutouts. The perimeter of the outer surface of the implant is a geometric shape. The cutout includes at least two angled faces and they have an arcuate shape. The implant further includes at least one hole or opening in communication with the outer surface and the inner surface. The implant is fabricate from biocompatible metal or another such material (see paragraph 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 5, 8, 20, 21, 28-31, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (Reference "WO 99/38461" cited on IDS).

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Paul et al. disclose the claimed invention except for the length ranging from about 11.5 to about 15.5 mm, the width ranging from about 8.0 to about 9.0 mm, and the depth ranging from about 5.5 to about 6.5 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Paul et al. having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claim 5, i.e. the geometric shape being a circle, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of Paul et al. having a geometric shape like a circle, since is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of adapting the implant to the implanting site. In re Dailey and Eilers, 149 USPQ 47 (1966). With regard to claims 8, 20, 21, 28-31 and 52, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Paul et al, from demineralized cortical bone, or biocompatible metal, or biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 3, 4, 7, 8, 13, 14, 16, 17, 21, 28-31, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (Reference US Patent "6,039,762" cited on IDS).

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Paul et al. disclose the claimed invention except for the geometric shape being an ellipse (claim 3), or the cutouts being arcuate shape (claims 16 and 17). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant of McKay having a geometric shape like an ellipse or the cutouts having an arcuate shape, since is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious. In re Dailey and Eilers, 149 USPQ 47 (1966). With regard to claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of McKay having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claims 7, 8, 13, 14, 21, 28-31, 51, and 52, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of McKay from bone allograft material, or demineralized cortical bone, or biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 3-8, 13, 14, 21, 28-31, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonenobu (Reference "JPO2000175943" cited on IDS).

Yonenobu et al. disclose the claimed invention except for the geometric shape being an ellipse, or a circle, or the implant being tubular shape. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant

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of Yonenobu et al. having a geometric shape like an ellipse or circle or the implant having a tubular shape, since is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of adapting the implant to the implant site. In re Dailey and Eilers, 149 USPQ 47 (1966). With regard to claim 4, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Yonenobu et al. having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. With regard to claims 7, 8, 13, 14, 21, 28-31, 51, and 52 it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Yonenobu et al. from bone allograft material, or demineralized cortical bone, or biocompatible polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed on February 23, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that Paul does not disclose an implant "configured to be insertable between first and second cut bone segments of a single vertebra", it is noted that the implant of Paul has the ability to perform the function recited in the claim if one so desire, e.g.

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one can insert the implant between first and second cut bone segments of a single vertebra.

Furthermore, it is noted that the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

Also, **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.**

Ex Parte Masham, 2 USPQ2d 1647 (1987).

In response to applicant’s argument that McKay does not disclose an implant “configured to be insertable between first and second cut bone segments of a single vertebra”, it is noted that the implant of McKay has the ability to perform the function recited in the claim if one so desire, e.g. one can insert the implant between first and second cut bone segments of a single vertebra.

Furthermore, it is noted that the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

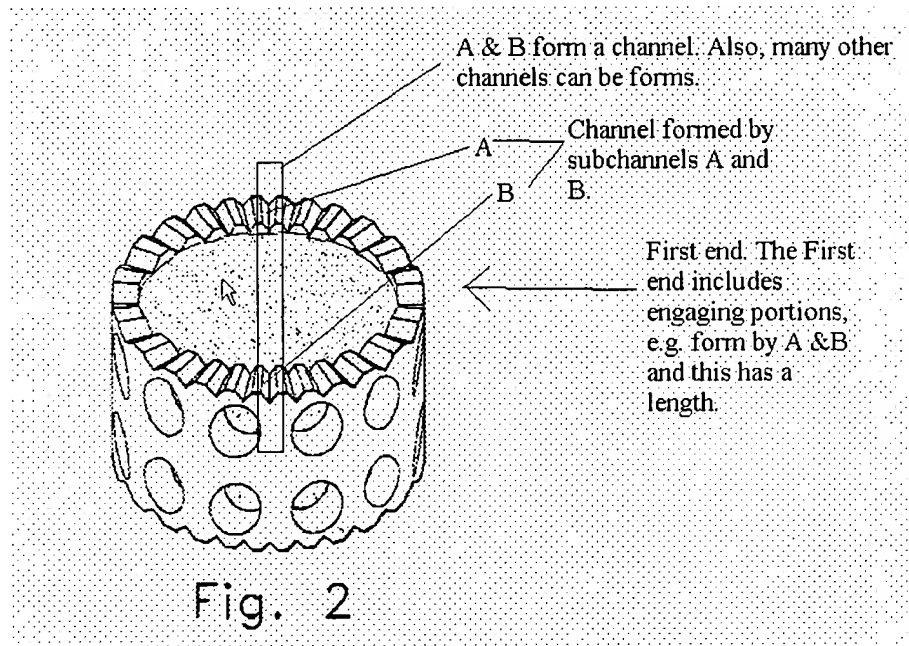
Also, **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations.**

Ex Parte Masham, 2 USPQ2d 1647 (1987).

In response to applicant’s argument that McKay does not have an implant comprising a body portion having first and second ends, the first and second ends comprising bone engaging portions each having a length, wherein at least one of the bone engaging portions comprises a bone receiving channel that extends a substantial portion of the length of the bone engaging portion and the channel configured and adapted to engage and retain at least one of the first and

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second cut bone segments, it is noted that McKay clearly shows an implant having the structural limitations set forth in the claims (see Figure 2 below).



Furthermore, with regard the functional language “configured and adapted to engage and retain at least one of the first and second cut bone segments”, it is noted that the implant of McKay has the ability to perform the function if one so desire. Furthermore, it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but **only requires the ability to so perform**. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Also, **the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations**. Ex Parte Masham, 2 USPQ2d 1647 (1987).

In response to applicant’s argument that Yonenobu does not disclose an inner surface configured to render the body portion substantially hollow, it is noted that Yonenobu clearly discloses an inner surface that render the body portion substantially hollow, i.e. the hollow

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portion is completely through the implant, thus it can be considered substantially hollow. Furthermore, in response to applicant's statement that the hole does not render the spacer "substantially hollow" rather it is solid, it is noted that this is only applicant's opinion and in the examiner opinion the body can be considered substantially hollow since the hole is through the whole body. Moreover, when you compare the implant of Yonenobu with one that does not have any openings or gaps, clearly the Yonenobu implant would be considered substantially hollow compared to one that is not hollow at all.

Applicant's arguments with regard to claims 3, 4, 5, 6, 7, 8, 13, 14, 16, 17, 20, 21, 28-31, 51, and 52 do not overcome the rejections applied thereto, since applicant has not provide any convincing showing that these are nothing more than optimum or workable values, or more than one of numerous shapes or configurations, or known materials as asserted by the examiner.

Applicant has not provided any showing that such limitations are "critical". In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). **Mere arguments by counsel cannot take the place of evidence.** In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

Allowable Subject Matter

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 23-25 and 27 are allowed.

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Claims 53-60 and 63-68, as understood, are allowed.

Claims 61 and 62 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

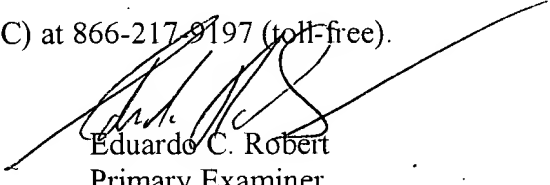
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.